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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,103	02/14/2005	Steven Gareth Griffiths	VA/H-32534A	5430

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ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,103	GRIFFITHS ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *9-16,18-23 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,17 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/11/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-8, 17 and 31-33, in the reply filed on 3/28/07 is acknowledged. The traversal is on the ground(s) that it would not place a serious burden on the Examiner to examine the subject matter of Group I, nucleic acid, and the subject matter of Group II, amino acids, together. This is not found persuasive because under PCT Rule 13.2, the inventions lack the same or corresponding special technical features for the following reasons: the Invention of Group I is not novel. WO 01/29233 A, WO 02/04018, and WO 01/68865 A all teach an isolated nucleic acid sequence encoding an Arthrobacter hsp70 protein. Accordingly, the inventions lack unity of invention. Further, the special technical feature of Group I is a nucleic acid which is biologically, structurally and chemically different from a protein which is the special technical feature of Group II. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. In addition, while a polypeptide of group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate

databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides having 85% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature.

The requirement is still deemed proper and is therefore made **FINAL**.

Claim(s) 9-16, 18-23 and 34 are withdrawn from consideration because they are drawn to a non-elected invention. Claims 1-8, 17, and 31-33 are currently under examination.

Claim Rejections - 35 USC § 112-2nd paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8, 17 and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it the mere recitation of a name, i.e., an isolated nucleic acid sequence encoding 'Arthrobacter hsp70 protein', to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing

and setting forth the inventive concept. The claim should provide any structural properties, such as the nucleic acid sequence or the amino acid sequence of the protein, which would allow for one to identify the isolated nucleic acid without ambiguity. The mere recitation of a name does not adequately define the claimed nucleic acid sequence. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 2 is vague and indefinite is also vague and indefinite because it fails to provide the structure for the claimed nucleic acid sequence or the protein it encodes, e.g., SEQ ID NO: X. The strain from which the nucleic acid is isolated from does not provide a description of the structure of the actual sequence. . While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claim 3 is vague and indefinite due to the phrase "a sequence having 85% homology thereto, or a sequence which under stringent conditions hybridizes with the sequence of SEQ ID NO: 1". First, there is no functional requirement for the homologous sequence. Does this sequence include deletions, substitutions, insertions,

etc.? Does it encode a functional protein, etc? The claim is also vague and indefinite because it is unclear what is encompassed by the phrase "stringent [hybridization] conditions". The phrase "stringent hybridization conditions" is vague and indefinite because hybridization conditions can vary considerably. A number of parameters govern the stringency of the hybridization including the hybridization temperature, hybridization time, washing temperature, washing time, formamide concentration, detergent concentration and salt concentration. Changes in these parameters will affect the specificity of the binding. Thus, in order to ascertain the metes and bounds of the patent protection, the skilled artisan would require knowledge of these specific parameters. The claim does not clearly and unambiguously set forth the appropriate reaction conditions. The rejection may be overcome by clearly setting forth the reaction conditions encompassed by a stringent hybridization, as supported by the disclosure.

Claim 3 is also vague and indefinite due the the phrase "or a fragment thereof which encodes amino acid 162 to 365 of Hsp70" because it is vague and confusing. The preceding language recites 'comprising SEQ ID NO: 1" so it is unclear whether amino acids 162 to 365 are intended to be from the particular amino acid sequence encoded by SEQ ID NO: 1, e.g., SEQ ID NO:2, or if they may be from *any* Hsp70 protein. Several different microorganisms possess an Hsp70 protein so it is unclear whether the claim encompasses sequences which comprise nucleic acid sequences which encode amino acids 162 to 365 from other microorganisms, e.g., M.tuberculosis, P.salmonis, etc.. It is suggested that "of Hsp70" be changed to "from SEQ ID NO: 2" in

order to overcome the rejection since this is what the non-elected claims and specification suggest was intended.

Claim 6 is vague and indefinite due to the phrase "wherein said antigen is IPNV VP2 or VP3". It is unclear what is encompassed by these abbreviations. The term "IPNV" should be spelled out in the claims the first time it is used, e.g., Infectious Pancreatic Necrosis Virus.

Claim Objections

4. Claim 17 is objected to because of the following informalities: Claim 17 depends on non-elected claim 11. The subject matter of claim 11 should be incorporated into the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112- Deposit Requirement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification lacks complete deposit information for the deposit of Arthrobacter strain ATCC 55921. Because it is not clear that the properties of this strain are known and publicly available or can be reproducibly isolated from nature without undue

experimentation and because the best mode disclosed by the specification requires the use of the specific strain, a suitable deposit for patent purposes is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of the deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

© the deposits will be maintained in a public depository for a period of at least thirty years from the date of the deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become non-viable or non-replicable.

In addition, a deposit of the biological material that is capable of self-replication either directly or indirectly must be viable at the time of the deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1)The name and address of the depository;
2)The name and address of the depositor;
3)The date of deposit;
4)The identity of the deposit and the accession number given by the depository;
5)The date of the viability test;
6)The procedures used to obtain a sample if the test is not done by the depository; and
7)A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 112-Enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-8, 17 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "an isolated polynucleotide

comprising the nucleic acid sequence set forth in SEQ ID NO: 1', 'an isolated polynucleotide which the amino acid sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 2 amino acids 162 to 365, does ***not*** reasonably provide enablement for 'an isolated nucleic acid sequence encoding [any] Arthrobacter hsp70 protein", "an isolated nucleic acid sequence which is 85% homologous to SEQ ID NO: 1 or any isolated nucleic acid sequence which hybridizes under [any] stringent conditions to SEQ ID NO: 1", nor is it enabled for isolated nucleic acid sequences which encode sequences with at least 85% homology to SEQ ID NO: 2 or amino acids 162-365 of SEQ ID NO: 2.

Vaccine compositions comprising any of the claimed expression vectors are not enabled, nor are methods of preventing *any* disease in a fish.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The breadth of the instant claims is drawn to polynucleotides that are not specified in the sequence disclosure. The specification states that substitutions, additions, or deletions may be made to the defined sequences; however, the specification provides no guidance as to what nucleic acids may be changed without causing a detrimental effect to the protein to be produced. Further, it is unpredictable as to which nucleotides/amino acids could be removed and which could be added. While it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of success are limited. Other positions are critical to the

protein's structure/function relationship, e.g., such as various positions or regions directly involved in binding, catalysis in providing the correct three-dimensional spatial orientation of binding and catalytic sites. These regions can tolerate only very little or no substitutions. To start with the DNA sequence first, this requires even more work on the part of the skilled artisan.

The instant claims are drawn to nucleic acids comprising a sequence with a given percent similarity to a nucleic acid which encodes a protein. Selective point mutation to one key residue could eliminate the function of the polypeptide. If the range of decreased binding ability after single point mutation of a protein antigen varies, one could expect point mutations in the protein antigen to cause varying degrees of loss of protection/function, depending on the relative importance to the binding interaction of the altered residue. Alternatively, the combined effects of multiple changes in an antigenic determinant could again result in loss of function. A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies in the polyclonal pool. As stated above, Applicants have not shown which nucleotides may be changed without causing a detrimental effect to the protein in which it encodes. The claims allow for as great as 15% variation. Applicants have provide no guidance to enable one of ordinary skill in the art how to determine, without undue experimentation, the effects of different nucleotide substitutions and the nature and extent of the changes that can be made. It is expensive and time consuming to make amino acid substitutions at more than one position, in a particular region of the

protein, in view of the many fold possibilities for change in structure and the uncertainty as to what utility will be possessed. See Mikayama et al. (Nov.1993. Proc.Natl.Acad.Sci. USA, vol. 90 : 10056-10060) which teaches that the three-dimensional structure of molecules is important for their biological function and even a single amino acid difference may account for markedly different biological activities. Rudinger et al. (June 1976. Peptide Hormones. Biol.Council. pages 5-7) also teaches that amino acids owe their 'significance' to their inclusion in a pattern which is directly involved in recognition by, and binding to, the receptor and the significance of the particular amino acids and sequences for different amino acids cannot be predicted *a priori*, but must be determined from case to case by painstaking experimental study. Given the lack of guidance contained in the specification regarding acceptable nucleotide substitutions, additions or deletions, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

The specification also does not enable vaccine compositions comprising DNA expression vectors comprising SEQ ID NO:1, fragments thereof which encode amino acids 162-365 of Hsp70 or a sequence having at least 85% homology thereto or a sequence which under stringent conditions hybridizes with the sequence of SEQ ID NO:1, nor do they enable a method of preventing *any* disease in a fish comprising administering the aforementioned vaccines. The instant specification at pages 24-25, Example 4, teaches that Atlantic salmon can be vaccinated intramuscularly with DNA expression vector/plasmids pUKrsxHSP70-ipnVP2 and pUKrsxHSP70-ipnVP3. The fish are challenged 4-6 weeks later by exposure to virulent IPNV (infectious pancreatic

necrosis virus) and results indicate that "all of the nucleic acid vaccines based on the VP2 sequence of IPNV are protective against challenge by the virus, including the hsp70-VP2 fusion. The results do not state that the hsp70-VPN3 vaccines were successful. The results indicate that the VP2 sequence is necessary to achieve protection against virulent IPNV. Accordingly, only vaccines comprising pUKrsxHSP70-ipnVP2 and methods of protecting against disease caused by infection with IPNV (infectious pancreatic necrosis virus) are enabled. The specification does not provide any other working examples for prevention or protection against any other disease in fish, nor does it provide results with the use of any other DNA expression vectors, including solely an expression vector comprising comprising SEQ ID NO:1, fragments thereof which encode amino acids 162-365 of Hsp70 or a sequence having at least 85% homology thereto or a sequence which under stringent conditions hybridizes with the sequence of SEQ ID NO:1. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." The vaccine art is

highly unpredictable and therefore actual results from challenge experiments are necessary to enable vaccines and methods of prevention/protection.

Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Claim Rejections - 35 USC § 112-Written Description

9. Claims 1-8, 17 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO: 1 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with the claims which encompass variants, derivatives, fragments and analogs from the full-length sequence, from hybrids or from epitope-bearing portions.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Furthermore, In The Reagents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

No disclosure, beyond the mere mention of allelic variants is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore, only "an isolated polynucleotide comprising the nucleic acid sequence set forth in SEQ ID NO: 1', 'an isolated polynucleotide which encodes the amino acid sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 2 amino acids 162 to 365', but not the full breadth of the claims meets the written description provisions of 35 USC 112, first paragraph.

10. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser
Primary Examiner
Art Unit 1645

4/27/06